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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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| Application Number | 10/008,140 |
| Filing Date | OCTOBER 18, 2001 |
| First Named Inventor | LIEVEN STUYVER, et al. |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 08841.105021 (PHAR 1040U) |

Sheet 1 of 7

U.S. PATENT DOCUMENTS

| Examiner Initials * | Cite No. ¹ | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM-DD-YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|------------------------|--------------------------|----------------------|--------------------------------------|---|--|---|
| | | Number | Kind Code ² (if known) | | | |
| DBJ | AA | 5,843,640 | | PATTERSON, et al. | 12-01-1998 | |
| DBJ | AB | 6,210,875 | | PATTERSON, et al. | 04-03-2001 | |
| DBJ | AC | 6,235,504 | | ZHANG, et al. | 05-22-2001 | |

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|------------------------|--------------------------|-------------------------|----------|--------------------------------------|---|--|---|----------------|
| | | Office ³ | Number | Kind Code ² (if known) | | | | |
| DBJ | AD | WO | 00/44936 | | Commissariat a l'energie | 08-03-2000 | | |
| DBJ | AE | WO | 00/68436 | | BOSBACH, et al. | 11-16-2000 | | |
| DBJ | AF | WO | 01/66799 | | SHAFER, et al. | 09-13-2001 | | |

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| DBJ | AG | ABE, A., et al. Quantitation of hepatitis B virus genomic DNA by real-time detection PCR. <i>J Clin Microbiol.</i> Sept. 1999, 37:2899-2903. | |
| | AH | ABERHAM, C., et al. A quantitative, internally controlled real-time PCR Assay for the detection of parvovirus B19 DNA. <i>J Virol Methods.</i> 2001, 92:183-191. | |
| | AI | BISSET, L. R., et al. Quantification of in vitro retroviral replication using a one-tube real-time RT-PCR system incorporating direct RNA preparation. <i>J Virol Methods.</i> 2001, 91:149-155. | |
| DBJ | AJ | BONNET, G., et al. Thermodynamic basis of the enhanced specificity of structured DNA probes, <i>Proc. Natl. Acad. Sci. USA</i> , May 1999, 96:6171-6176. | |

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| ms | AK | CANE, P.A., et al. Use of real-time PCR and fluorimetry to detect lamivudine resistance-associated mutations in hepatitis B virus., <i>Antimicrobial Agents and Chemotherapy</i> . July 1999, 43:1600-1608. | |
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| | AP | GAULT, E., et al. Quantification of Human Cytomegalovirus DNA by Real-Time PCR. <i>J Clin Microbiol</i> . Feb. 2001, 39:772-775. | |
| | AQ | GELMINI, S., et al. Quantitative polymerase chain reaction-based homogeneous assay with fluorogenic probes to measure c-erbB-2 oncogene amplification. <i>Clin Chem</i> 1997, 43:752-758. | |
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|---------------------|-----------------------|---|----------------|
| mm | AU | GRUBER, F., et al. Quantitation of Viral DNA By Real-Time PCR Applying Duplex Amplification, Internal Standardization, and Two-Color Fluorescence Detection. <i>Appl Environ Microbiol.</i> 2001, 67:2837-2839. | |
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| | AX | JABS, W. J., et al., Normalized Quantification by Real-Time Pcr of Epstein-Barr Virus Load in Patients at Risk for Posttransplant Lymphoproliferative Disorders. <i>J Clin Microbiol</i> , 2001, 39:564-569. | |
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| | AZ | JU, J., et al. Fluorescence Energy Transfer Dye-Labeled Primers for DNA Sequencing and Analysis, <i>Proc. Natl. Acad. Sci. USA</i> , May 1995, 92:4347-4351. | |
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| | BD | KIMURA, H., et al. Quantitative Analysis of Epstein-Barr Virus Load by Using a Real-Time PCR Assay, <i>J. Clin. Microbiol.</i> , Jan. 1999, 37:132-136. | |
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| mm | BF | KOSTRIKIS, L.G., et al., Spectral Genotyping of Human Alleles, <i>Science</i> , Feb. 1998, 279:1228-1229. | |

Examiner Signature

Diana P...

Date Considered

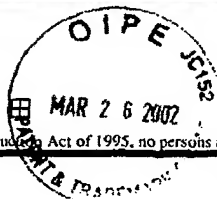
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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

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|---------------------|-----------------------|---|----------------|
| DP | BG | KUIMELIS, R. G., et al., Structural Analogues of TaqMan Probes for Real-Time Quantitative PCR, <i>Nucleic Acids Symp. Ser. No. 37</i> , 1997, 37:255-256. | |
| | BH | LALLEMAND, F., et al., Quantitative Analysis of Human Herpesvirus 8 Viral Load Using a Real-Time PCR Assay, <i>J. Clin. Microbiol.</i> April 2000, 38:1404-1408. | |
| | BI | LEONE, G., et al., Molecular Beacon Probes Combined With Amplification by NASBA Enable Homogenous, Real-Time Detection of RNA, <i>Nucleic Acids Research</i> , 1998, 26:2150-2155. | |
| | BJ | LEWIN, S. R., et al. Use of Real-Time PCR and Molecular Beacons to Detect Virus Replication in Human Immunodeficiency Virus Type 1-Infected Individuals on Prolonged Effective Antiretroviral Therapy. <i>J. Virol.</i> , July 1999, 73:6099-6103. | |
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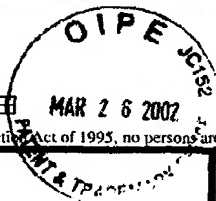
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|---------------------|-----------------------|---|----------------|
| DM | BQ | MARTELL, M., et al. High-Throughput Real-Time Reverse Transcription-PCR Quantitation of Hepatitis C Virus RNA. <i>J. Clin. Microbiol.</i> , Feb. 1999, 37:327-332. | |
| | BR | MATSUO, T., In Situ Visualization of Messenger RNA for Basic Fibroblast Growth Factor in Living Cells, <i>Biochimica et Biophysica Acta</i> , 1998, 1379:178-184 | |
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| | BT | MORRIS, T., et al. Rapid Reverse Transcription-PCR Detection of Hepatitis C Virus RNA in Serum by Using the TaqMan Fluorogenic Detection System, <i>J. Clin. Microbiol.</i> , Dec. 1996, 34:2933-2936. | |
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| | BW | NICOLL, S., et al., Detection of Herpes Viruses in Clinical Samples Using Real-Time PCR, <i>J. Virol. Methods</i> , 2001, 96:25-31. | |
| | BX | NIESTERS, H.G.M., et al., Development of a Real-Time Quantitative Assay for Detection of Epstein-Barr Virus, <i>J. Clin. Microbiol.</i> , Feb. 2000, 38:712-715. | |
| | BY | NITSCHKE, A., et al., Detection of Human Cytomegalovirus DNA by Real-Time Quantitative PCR, <i>J. Clin. Microbiol.</i> , July 2000, 38:2734-2737. | |
| DS | BZ | NUOVO, G.J., et al., In Situ Amplification Using Universal Energy Transfer-Labeled Primers, <i>J. Histochem. & Cytochem.</i> , 1999, 43:273-279. | |

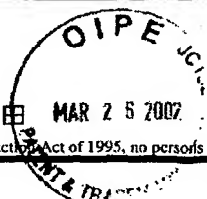
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| DS | CA | OBERST, R.D., et al., PCR-Based DNA Amplification and Presumptive Detection of <i>Escherichia coli</i> O157:H7 with an Internal Fluorogenic Probe and the 5' Nuclease (TaqMan) Assay, <i>Applied and Environmental Microbiology</i> , Sept. 1998, 64:3389-3396. | |
| | CB | OHYASHIKI, J.H., et al. Use of Real-Time PCR to Monitor Human Herpesvirus 6 Reactivation After Allogeneic Bone Marrow Transplantation, <i>Int. J. Mol. Med.</i> , 6:427-432, (2000) | |
| | CC | PE APPLIED BIOSYSTEMS, User Bulletin #2 ABI PRISM 7700 Sequence Detection System, December 11 1997, 1-36. | |
| | CD | PEVENSTEIN, S. R., et al., Quantitation of Latent Varicella-Zoster Virus And Herpes Simplex Virus Genomes in Human Trigeminal Ganglia, <i>J. Virol.</i> , Dec. 1999, 73:10514-10548. | |
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| | CF | SAHA, B.K., et al. Quantitation of HIV-1 by Real-Time PCR With a Unique Fluorogenic Probe, <i>J. Virol. Methods</i> , 2001, 93:33-42. | |
| | CG | SAULEDA, S., et al., Profiles of GBV-C/hepatitis G virus Markers in Patients Coinfected With Hepatitis C Virus, <i>J. Med. Virol.</i> , 1999, 59:45-51. | |
| | CH | SCHUTTEN, M., et al., Development of a Real-Time Quantitative RT-PCR for the Detection of HIV-2 RNA in Plasma, <i>J. Virol. Methods</i> , 2000, 88:81-87. | |
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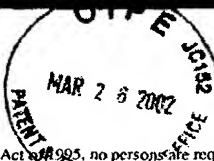
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| | | Application Number | 10/008,140 |
| | | Filing Date | OCTOBER 18, 2001 |
| | | First Named Inventor | LIEVEN STUYVER, et al. |
| | | Group Art Unit | |
| | | Examiner Name | |
| Sheet 7 of 7 | Attorney Docket Number | 08841.105021 (PHAR 1040U) | |

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| Examiner Initials * | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ⁶ |
| DM | CK | SWAN, D.C., et al. A Sensitive, Type-Specific, Fluorogenic Probe Assay for Detection of Human Papillomavirus DNA, <i>J. Clin. Microbiol.</i> , 1997, 35:886-891. | |
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| Examiner Signature | Diana Bjt | Date Considered | 4/9/03 |
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